

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| | | |
|-----------------------------------------------------------|--------------------------------------------------------------------------------------------------|----------------------------------------------------------------|
| Applicant's or agent's file reference RLL-405WO | FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below. | |
| International application No. PCT/IB2004/002191 | International filing date (day/month/year) 01/07/2004 | (Earliest) Priority Date (day/month/year) 01/07/2003 |
| Applicant RANBAXY LABORATORIES LIMITED | | |

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. Certain claims were found unsearchable (See Box II).

3. Unity of invention is lacking (see Box III).

4. With regard to the title,

the text is approved as submitted by the applicant.

the text has been established by this Authority to read as follows:

5. With regard to the abstract,

the text is approved as submitted by the applicant.

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regards to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. _____

as suggested by the applicant.

as selected by this Authority, because the applicant failed to suggest a figure.

as selected by this Authority, because this figure better characterizes the invention.

- b. none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

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|---------------------------------------------------|
| International Application No PCT/IB2004/002191 |
|---------------------------------------------------|

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|--------------------------------------------|
| A. CLASSIFICATION OF SUBJECT MATTER |
| IPC 7 A61K31/7048 A61K9/00 A61K9/20 |

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

CHEM ABS Data, EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| X | <p>DATABASE CA 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; "Azithromycin tablet compositions" retrieved from STN Database accession no. 135:200437 XP002308007 abstract & IL 119 866 A1 (UNIPHARM LTD., ISRAEL) 31 December 1999 (1999-12-31)</p> <p>---</p> <p>WO 02/10181 A (BANON PARDO GABRIEL ; GELPI VINTRO JOSE MARIA (ES); SINT QUIMICA SA (E) 7 February 2002 (2002-02-07) page 10, line 1 - line 5</p> <p>---</p> <p>-/-</p> | 1-4, 6-11, 15-18, 33 |
| X | | 1, 19, 33 |

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the International search

29 November 2004

Date of mailing of the International search report

28/12/2004

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Boulois, D

INTERNATIONAL SEARCH REPORT

National Application No

PCT/IB2004/002191

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| X | EP 0 984 020 A (APOTEX INC) 8 March 2000 (2000-03-08) claim 9 --- | 1, 19, 33 |
| X | WO 03/032922 A (KHONDO LEV ; LESSEN TANIA (CA); SCHWARZ JOSEPH (CA); MATHIVANAN MATHI) 24 April 2003 (2003-04-24) cited in the application claim 7 examples --- | 1-4, 7-11, 14-22, 26-33 |
| P, X | WO 2004/035063 A (SANDOZ AG ; SUMMER HARALD (AT); ZEISL ERICH (AT); GOPINATHAN DINESH (I) 29 April 2004 (2004-04-29) the whole document --- | 1-4, 7, 8, 10, 15-22, 24-26, 28-33 |
| P, X | WO 03/053399 A (JOHNSON BARBARA ALICE ; PFIZER PROD INC (US); FERGIONE MICHAEL BRUCE () 3 July 2003 (2003-07-03) examples --- | 1-4, 6-11, 14-22, 24-33 |
| P, X | WO 03/063838 A (JOHNSON BARBARA ALICE ; QUAN ERNEST SHING (US); PFIZER PROD INC (US)) 7 August 2003 (2003-08-07) examples --- | 1-4, 8-22, 26-33 |
| P, X | WO 03/053416 A (JOHNSON BARBARA ALICE ; QUAN ERNEST SHING (US); PFIZER PROD INC (US);) 3 July 2003 (2003-07-03) examples --- | 1-4, 8-22, 26-33 |
| A | EP 0 582 396 A (PFIZER) 9 February 1994 (1994-02-09) the whole document --- | 1-33 |
| P, X | WO 2004/000865 A (RANEBURGER JOHANNES ; SCHWARZ FRANZ XAVER (AT); SANDOZ AG (AT)) 31 December 2003 (2003-12-31) the whole document --- | 1-4, 8-22, 26-33 |

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2004/002191

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
Although claim 33 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

National Application No

PCT/IB2004/002191

| Patent document cited in search report | | Publication date | | Patent family member(s) | | Publication date |
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Information on patent family members

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| Patent document cited in search report | Publication date | Patent family member(s) | | Publication date |
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